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Oscar Hernandez
Risk Assessment Division
US Environmental Protection Agency
HPV Challenge

Subject: Revised Test Plan and Robust Summaries for Irganox 1035
Thiodiethylene bis (3,5-di-tert-butyl-4- hydroxyhydrocinnamate)
CAS No. 41484-35-9

Dear Dr. Hernandez:

Ciba Specialty Chemicals Corporation supports EPA's High Production Volume (HPV) chemical challenge program and the effort to gather and publish basic hazard information on those chemicals manufactured at high volumes in the United States. Ciba Specialty Chemicals Corporation is the sponsor for Thiodiethylene bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate). Enclosed are a revised test plan and robust summaries for Irganox 1035. The revisions address the agency's comments published January 22, 2004.

In response to EPA's comments regarding the water solubility of this chemical we have conducted new testing. This work is described in a revised robust summary which is included in this submission. Also provided in this submission is a revised robust summary on the stability and hydrolysis of the compound.

Regarding the Health Effects data, the agency indicated that the in vivo Nucleus Anomaly Test was inadequate and it was recommended that a new study be conducted. The cytogenetic testing available for the Ciba-sponsored HPV hindered phenol compounds CAS 2082-79-3 and CAS 6683-19-8 has demonstrated that these compounds are not clastogenic. Furthermore, chronic bioassays have demonstrated that these materials are not carcinogenic.

Additional supporting data relating to hindered phenol antioxidants has been presented for the HPV Hindered Phenol Category, sponsored by the American Chemistry Council. We believe the in vivo Nucleus Anomaly Test submitted previously, is scientifically sound and provides relevant supporting evidence on the potential for Irganox 1035 to cause chromosomal damage, despite the agency's criticism of this study. This body of information indicates a low concern for clastogenic effects and collectively fulfills the requirement for chromosomal aberration testing.

EPA also recommended a combined reproductive/developmental toxicity (OECD TG 421) study for this chemical. Specific reproduction and developmental tests are not available for Irganox 1035, however, analysis of reproductive organs in the existing 90-day studies for Irganox 1035 demonstrates that gonadal effects do not occur. Furthermore, adequate information on reproductive and developmental toxicity is also available for other structurally-related chemicals in the HPV program (CAS 2082-79-3[1], CAS 6683-19-8[1] and CAS 32687-78-8) which are also sponsored by Ciba. This information demonstrates that hindered phenol compounds of this type are not reproductive or developmental toxins.

In conclusion, Ciba believes that acceptable testing and read-across data are available to fulfill all HPV endpoints. Furthermore, the available data do not raise concerns for adverse effects on man or the environment from the product as presently used. Finally, Irganox 1035 will undergo a comprehensive assessment in the REACH program and relevant new testing undertaken as part of that initiative will be provided to EPA for inclusion in the HPV program.

Sincerely yours,

Richard Balcomb

[1] Ciba Specialty Chemicals is now supporting CAS 2082-79-3 and CAS 6683-19-8 in the OECD SIDS program.